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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,386	01/16/2002	Philip Gerard Cavanaugh		1684

7590 02/18/2005
Philip G. Cavanaugh
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Redford, MI 48239

EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/046,386

Applicant(s)

CAVANAUGH, PHILIP GERARD

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-42 is/are pending in the application.
- 4a) Of the above claim(s) 32-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-31 is/are rejected.
- 7) ☒ Claim(s) 32-42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of invention group I, directed to method of making transferrin-chlorin conjugate in the reply filed on March 5, 2004, and the election without travers of the particular specied in the reply filed June 30, 2004 is acknowledged.

Disclosure Objections

1. The disclosure is objected to because of the following informalities: the recitation of US Patent 5,528,453 at page 6, line 6 appears to be incorrect as the inventor of this US patent does not match what listed herein.

Appropriate correction is required.

Claim Objections

2. Claims 32-42 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

3. Claim 26-31 are objected to for minor informalities. The employment of parenthetical expression, e.g., (hereafter referred to as QAE sepharose), in claims is considered informal. It is suggested that the expression employed through out the claims be consistent. Do not change the expression in the claims, e.g., using full name in one claim and the abbreviation in others.

Claim Rejections 35 U.S.C. 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 25-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 25 recites "coupling agent-modified chlorin e6." The recitation lack support for the application as originally filed.

6. Claims 25-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "coupling agents" recited in the original claim 2, and the modified chlorin e6 derived from those compounds, does not reasonably provide enablement for any other compounds, which may function as coupling agents, or any other modified chlorin e6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,

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- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The claims are directed to a new procedure for conjugating a particular protein, i.e., transferrin with chlorin e6, wherein the transferrin retaining its bioactivity (pages 4-5 herein). Only EDC was used in the example as the coupling agent (page 18-20). The claims read on any compounds that may be used to link the transferrin and chlorin e6, and not affect the activity of transferrin.

Applicants fail to provide information allowing skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only one coupling agent example is set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed of physiological activity. The instant claims read on all coupling agents meet the requirements herein, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention, absent undue experimentation.

7. Claims 25-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the “iron saturated human transferrin” as disclosed at page 18 herein, does not reasonably provide enablement for any other transferrins, which may be suitable for the instant process. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

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commensurate in scope with these claims without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The claims are directed to a new procedure for conjugating a particular protein in a particular form, i.e., iron saturated human transferrin with chlorin e6, wherein the transferrin retaining its bioactivity (pages 4-5 herein). Only iron saturated human transferrin was used in the example (page 18-20). The claims read on any transferrins that may be suitable in the instant process. Applicants fail to provide information allowing skilled artisan to ascertain these transferrin without undue experimentation. In the instant case, only one transferrin example is set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed of physiological activity. Note there are more than a thousand transferrins, and each of them has its unique properties. Further, it would

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have reasonably expected that iron-saturated transferrin would behave different from transferrin without binding iron. The instant claims read on all transferrin, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention, absent undue experimentation.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 25-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 25 recites step D, which is an independent step from steps A, B, and C. It appears that if steps A, B, and C are carried out, step D cannot be carried out. Therefore, step D is an alternative of step A, B, and C. The claim is indefinite as to the function of step D in the claimed method. It is suggested that a separated claims for method using step D.

11. Claim 25 recites "from claim 25 A," "from claim 25 B," and "from claim 25 G." such recitation is confusing and indefinite because no one know what is "claim 25 A," "claim 25 B," and "claim 25 G." If these are what applicant intended, please use "from step A" "from step B," and "from step G."

12. Steps G and K in claim 25 require "the solution of choice," However, the claim or the specification fails to provide the standard as to the "choice" herein recited.

13. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim

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does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 26-31 recites the broad recitation "but not limited to", and the claim also recites "is" which is the narrower statement of the range/limitation.

14. Claims 25-31 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

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Information Disclosure

The examiner noted that the application lists many background references which may be considered to be relevant to the patentability of instant application. Listing references, which are relevant to the patentability of the claimed invention, in the application does not mean applicant has met the information disclosure requirement set forth in 37 C.F.R. 1.56. To meet the requirements, applicant need to submit a separated list of the references, preferably, in form 1449, and with full copies of non-US patent references listed therein.

Allowable subject matters.

The particular method of claim 25 with the particular elected species herein, and wherein the transferrin is iron saturated human transferrin, is allowable.

15. The following are suggested formats for either a Certificate of Mailing or Certificate of Transmission under 37 CFR 1.8(a). The certification may be included with all correspondence concerning this application or proceeding to establish a date of mailing or transmission under 37 CFR 1.8(a). Proper use of this procedure will result in such communication being considered as timely if the established date is within the required period for reply. The Certificate should be signed by the individual actually depositing or transmitting the correspondence or by an individual who, upon information and belief, expects the correspondence to be mailed or transmitted in the normal course of business by another no later than the date indicated.

Certificate of Mailing

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on _____
(Date)

Typed or printed name of person signing this certificate:

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Signature: _____

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I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office, Fax No. (703) _____ - _____ on _____.
(Date)

Typed or printed name of person signing this certificate:

Signature: _____

Please refer to 37 CFR 1.6(d) and 1.8(a)(2) for filing limitations concerning facsimile transmissions and mailing, respectively.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1617

SHENGJUN WANG
PRIMARY EXAMINER